HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service 1875b
Food and Drug Administration

Refer to: CFN 1123466

Baltimore District Office
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

June 17, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Harold McBee, President
Midstate Medical, Inc.
104 Log Canoe Circle
Stevensville, Maryland 21666

Dear Mr. McBee:

The Food and Drug Administration (FDA) conducted an inspection of your Keyser, West Virginia facility on June 9, 1998. During the inspection, the following deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211) were observed. These deviations cause your Compressed Oxygen USP to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act):

1. Failure to calibrate the oxygen analyzer in accordance with the manufacturer's instruction manual and to maintain appropriate documentation of the calibration of instruments used to test and release the drug product.

2. Failure to perform or to have appropriate documentation to demonstrate that adequate pre-fill, fill, and post-fill operations were performed on each high-pressure cylinder filled.

3. Failure to establish written procedures for the production and process controls designed to assure that the drug product has the identity, strength, quality, and purity it purports or is represented to possess.

4. Failure to establish written procedures designed to assure that correct labels and labeling are used, including identification of the drug product with a lot or control number that permits determination of the history of manufacture and control of the batch.

At the conclusion of the inspection, Mr. Marlin L. Bender, Technical Director, was given a written list of inspectional observations, Form FDA-483 (enclosed), which was discussed with him.

The aforementioned violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction. Enclosed is a document provided by FDA National Expert, Mr. Duane Sylvia, titled "FRESH AIR '98" which discusses the applicability of the Current Good Manufacturing Practice Regulations to medical gas manufacturers.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 379-1627, extension 14.

Sincerely,

Carl E. Draper
Acting Director, Baltimore District

Enclosures

cc: **(CERTIFIED MAIL - RETURN RECEIPT REQUESTED)**
Mr. Marlin L. Bender, Technical Director
Midstate Medical, Inc.
91 St. Cloud Street
Keyser, WV 26726